

Application No.: 10/822,200
Amendment and Response filed on February 15, 2006
Reply to Office Action of November 15, 2005
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REMARKS

Reconsideration of the application as amended is respectfully requested.

Status of the Claims

Claims 29-44 are presently pending. Claims 1-28 have been previously cancelled. New claims 45-49 have been added herein.

Discussion of the Amendments to the Claims

The claims have been amended to point out more particularly and to claim more distinctly the subject matter of the present invention. In particular, independent claims 29 and 41 have been amended to recite that the multi-layered graft includes a self-sealing gel selected from the group consisting of gelatin, collagen, albumin, casein, algin, carboxymethyl cellulose, carageenan, furcellan, agarose, guar, locus bean gum, gum arabic, hydroxyethyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyalkylmethyl cellulose, pectin, partially deacetylated chitosan, starch and starch derivatives, including amylase and amylopectin, xanthan, polylysine, hyaluronic acid, and its derivatives, heparin, their salts, and mixtures thereof. Moreover, new claims 45-49 have been added herein. Support for the amendments to the claims may be found in the subject application as published (i.e., in U.S. Publication No. 2004/0193242) at, for example, paragraphs [0054] and [0057] and at Tables 1 and 2.

The amendments to the claims do not warrant additional searching because amended claims 29 and 41 and new claims 45-46 all require a multi-layered graft having two ePTFE tubular structures having different internodal distances, and all previous searches for the same would have encompassed searches pertinent to the subject matter recited in those claims. Similarly, new claims 47-49 all require a multi-layered graft having two ePTFE tubular structures having different porosities, and all previous searches for the same would have

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encompassed searches pertinent to the subject matter recited in those claims.

Discussion of the Rejection Under 35 U.S.C. § 103(a)

Claims 29-44 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,619,641 to Schanzer (hereinafter "Schanzer") in view of U.S. Patent No. 6,521,284 to Parsons et al. (hereinafter "Parsons") and U.S. Patent No. 4,816,339 to Tu et al. (hereinafter "Tu"). In particular, the Examiner continues to allege that Schanzer discloses a first tubular structure having a first "thickness/porosity" and a second tubular structure having a second "thickness/porosity" wherein a resealable layer made of silicone is interposed between the tubular structures. (Office Action, page 2).

Moreover, the Examiner contends that Parsons discloses a flowable gel and that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to create a self-sealing flowable layer that adheres to the first and second layers because the flowable gels are known to deform elastically and then recover to their original form." (Office Action, page 3). The Examiner also alleges that porosity is synonymous with internodal distance and that Tu discloses grafts having layers having different internodal distances. The rejection under 35 U.S.C. §103(a) is respectfully traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness, the Examiner must establish that the cited combination of references teach or suggest every limitation of the claimed invention. Moreover, the Examiner must establish not only that there is some motivation to combine the teachings of the cited references, but also that there is a reasonable expectation of achieving the claimed invention upon doing so. *See* M.P.E.P. § 2142.

Although Schanzer discloses a graft that may be formed of two PTFE tubes, there is no disclosure, teaching or suggestion with regard to internodal distances. Rather, Schanzer

discusses wall thickness. Wall thickness, however, is distinct from internodal distance. Moreover, contrary to the Examiner's contention, although porosity may be controlled by controlling the internodal distance of a material (see paragraph [0005] of the subject application as published), porosity and internodal distance are distinct terms with distinct meanings. There is simply no disclosure, teaching or suggestion in Schanzer of a multi-layered ePTFE graft including two ePTFE tubular structures having a self-sealing material in between and having different internodal distances. In fact, the Examiner acknowledges that the term internodal distance does not even appear in Schanzer.

Moreover, neither Parsons nor Tu cure the deficiencies of Schanzer. In particular, there is no teaching in either of those references of a multi-layered ePTFE graft having a first ePTFE tubular structure, a second ePTFE tubular structure, and a self-sealing material interposed in between, wherein the tubular structures have different internodal distances. In fact, given the disparate teachings of each of those references, one of ordinary skill in the art would not even be motivated to combine their disclosures, let alone have a reasonable expectation of arriving at the subject invention from the prior art.

However, in an effort to advance prosecution and not in acquiescence of any rejection, the claims have been amended herein to clarify the claimed subject matter. As amended, independent claims 29 and 41 are directed to a multi-layered ePTFE graft that has a self-sealing gel interposed between two ePTFE tubular structures having different internodal distances, wherein the gel is selected from the group consisting of gelatin, collagen, albumin, casein, algin, carboxymethyl cellulose, carageenan, furcellan, agarose, guar, locus bean gum, gum arabic, hydroxyethyl cellulose, hydroxypropyl cellulose, methyl cellulose, hydroxyalkylmethyl cellulose, pectin, partially deacetylated chitosan, starch and starch derivatives, including amylase and amylopectin, xanthan, polylysine, hyaluronic acid, and its derivatives, heparin, their salts,

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and mixtures thereof. As there is no disclosure, teaching or suggestion in any of the cited references of the same, independent claims 29 and 41 and the claims dependent thereon are not obvious in view of those references. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

Concluding Remarks

The claims are believed to be allowable over the art and the application in good and proper form for allowance. The Examiner is invited to contact the undersigned if he has any questions regarding this submission or, if in his opinion, a teleconference call would expedite prosecution of the subject application.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17, and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,


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